TRANSFER OF HEALTH CARE TECHNOLOGY IN UNIVERSITY-INDUSTRY RESEARCH COLLABORATION ENVIRONMENT

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Abstract- **The traditional innovation research has focused on the diffusion process and adoption of new technologies. This paper deals with health care technology in the early innovation stages preceding targeted development and marketing. A model of early research processes in the biomedical field and determinants of technology transfer will be presented. The study material is eleven projects in the Competence Center Noninvasive Medical Measurements (NIMED), Linköping University, which is a collaboration center where academic researchers cooperate with industry and clinical departments. Data collection was made through semi-structured interviews. A qualitative approach has been adopted for data analysis. Research initiative of the investigated projects do in most cases originate in the academic knowledge base and earlier connections in industry and health care play an important role in formation of cooperation constellation. A number of internal factors are perceived as positive to project advancement, such as stable economy, proximity to clinical departments, and positive feedback from collaboration partners. Significant negative factors are all related to changes in cooperation structure. Clusters of related projects seem to be beneficial to research work and is an evident external factor which has to be added in a new model of technology transfer.**

Keywords – **Technology transfer, innovation, medical devices, biomedical engineering, clinical procedures, qualitative study**

I. INTRODUCTION AND AIM

Innovation research in the field of biomedical engineering has so far mainly focused on the diffusion and adoption of new technologies in the health care sector. The actors, events and decisions involved previous to the diffusion phase are probably equally important, though paid less attention. Early 20th century innovation research [1, 2] gave rise to the concept of innovation as a linear sequence of defined stages (Fig. 1), which is a gross simplification, but still the predominant image. The model indicates that research and development are performed quite unaffected by outside influences in the separate laboratory or clinical department. In reality lots of outside regulations and incentives affect decision making in the research projects and the actual prototype may return in multiple circles back to an earlier stage of the model.

Research on innovation and diffusion emanates mainly from the science disciplines of sociology and economics. As diffusion neither is a mere economic phenomenon nor can be separated from economy aspects, the choice in this paper is to integrate features common to both disciplines. Key concepts in general innovation research is [3, 4]: knowledge accumulation, knowledge synthesis, uncertainty, and discontinuity. This is in every aspect applicable to health care technology. Each new medical technology is the result of knowledge accumulation in several areas and involves a great deal of uncertainty and change of behavior.

Fig. 1. A linear-sequential model of innovation.

Three determinants of technology diffusion have been identified: the actors in the process, structure of the research environment, and the characteristics of the innovation [4]. These determinants are most probably also the main factors influencing the initiation phase of a research project.

The initiating forces in a research project are thought of as either "demand-pull" or "science-push" [5]. Demand factors include the priorities and needs of the end users and/or providers of health care. Science-push includes the creation of new technological or commercial opportunities by scientific research.

Interventions directed to stimulation of technology transfer from university to industry have been introduced in several countries. In most Western Europe countries financial and advisory aid to research-collaboration projects is almost exclusively controlled by the public sector. These measures often fail to be the incentives intended, which might depend on a rigid university system and/or the entrepreneurial climate [6]. An additional factor is probably the lack of understanding of how technologies are generated. A lot of academic discoveries are never transferred to an entrepreneur who can exploit the idea and academic researchers have often no business experience or lack interest in becoming entrepreneurs.

This paper deals with the research initiation phase from idea to targeted development of a new product. As pointed out by Rogers [7] these early events may have a considerable influence on the diffusion potential of new technologies. The most important characteristics explaining adoption rate of innovations (Table I) may also have an impact on technology transfer at different stages of the innovation process.

Study objectives are to give a description of the research process in the field of biomedical engineering and to identify determinants of technology transfer. The study material consists of eleven university-industry collaboration projects in the Competence Center of Noninvasive Medical Measurements (NIMED) at the University of Linköping. First part of the study has focused on the actors, events and environment in the initiation phase of the innovation process. Technology

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Abstract

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TABLE I
CHARACTERISTICS OF INNOVATIONS AND THEIR EFFECT ON TECHNOLOGY TRANSFER.

Relative advantage	The new technology must be perceived as advantageous to make actors adopt and develop the idea.
Compatibility	Consistence with existing values and norms is essential for adoption.
Complexity	The level of comprehension influences willingness to adopt a new technology.
Trialability	Opportunities to try out on a limited basis will lower the risk involved in adopting an unknown technology.
Observability	Visibility stimulates peer discussion around the innovation.

Adapted from Rogers 1983 [7]

characteristics have also been investigated in order to get a comprehensive picture of the study material. In the initial phase the most important questions at issue are:

1) *Environment:* What characteristics could be found in the collaboration structure of the research environment?
2) *Model:* What improvements can be added to the current image of early innovation?
3) *Guidelines*: What events have been beneficial to the projects? Have there been any evident impediments?

II. METHODOLOGY

A qualitative method has been adopted for collection and analysis of data. The approach is a dynamic theoretical perspective in the frame of holistic structuralism [8, 9]. An image of the course and performance of each project is built up by close investigation of networks, i.e. of separate features and their mutual relations. Observations are compared to and synthesized with current conceptions through a thorough study of literature in the field of innovation.

Data collection was made through semi-structured interviews and study of project documents (applications, contracts etc.). The interviewees were senior researchers in charge of the projects. They were selected to the interviews on behalf of their comprehensive knowledge of the projects. Furthermore, contacts with Ph.D. students and other personnel have yielded valuable input to the overall pictures.

The interviews explored eight themes:

1. *Cooperation structure*
2. *Research initiative*
3. *Planning*
4. *Tests and measurements*
5. *Documentation*
6. *Assessments*
7. *Rules and legislation*
8. *Diffusion of results*

The interviewees were also asked for any positive or negative aspects on how work was proceeding in the projects. The themes were chosen on basis of the literature study. New themes and follow-up questions were allowed. Duration of the interviews was approximately one hour per project. The interviews were performed by one senior researcher and one Ph.D. student, both with engineering experience and knowledge about the biomedical field.

Text analysis was performed through coding of the answers into categories within the themes. A comparison of information was made in order to find similarities and a possible correspondence in type of project and/or cooperation structure. The coding was performed by the Ph.D. student and checked by the senior researcher. Systematic analysis is also to be performed with the assistance of a data indexing and theorizing software.

III. MATERIAL

In the Competence Center NIMED academic researchers cooperate with industry and clinical research departments in a variety of projects based on non-invasive or minimal invasive medical technologies. The center was established to facilitate technology transfer and promote creation of vital collaboration projects. Medical field technology may be divided into three subgroups: drugs and biologicals, medical devices, and clinical procedures. Technologies in the NIMED projects are in most cases classified as “medical devices”, though some are working on optimization of use of an existing health care technology and thus are bordering the “clinical procedures” group.

The eleven research projects included in the study so far are all university based within the NIMED center. Each project has an industry collaboration partner and the opportunity to clinic cooperation within the university hospital. Senior researchers at the Department of Biomedical Engineering and other faculty engineers exercise project management. Some are in charge of more than one project. At least one Ph.D. student is involved in each project. Educational background of the students varies, though the greater part is university-trained engineers.

IV. RESULTS

Investigation of development phase of the projects at the time of the interviews revealed that most projects are in the early research phase. A striking feature of the cooperation structure is that university researchers contribute most of the work in this early innovation phase. Contribution from industry consists mainly of competence regarding demand, need and market. In the commercial stages the university contribution will probably be reduced, as the company will be more involved in development and marketing of the product.

Cooperation initiative often come from the university and is based on earlier connections. In a few cases there is an obvious demand for the innovation, but target user are significantly often found to be future research, even though all projects also have a potential medical application for their end product (Table II).

Project ideas originate mainly in university research. The knowledge base appears to be exclusively academic, though, in a few cases the industry partner specified the project work. Conversation around the theme of planning revealed that many projects do not have defined project goals and that the project schedule is ascribed a moderate importance. Research activity at the time of the interviews ranged from laboratory tests to

TABLE II
SELECTION OF CODING OF THE INTERVIEWS

Number of projects coded under respective category					
Cooperation structure			Research initiative		
Size of industry collaboration partner (employees)	<500	7	Source of initiative[1]	Academic	9
	>500	4		Industry	4
				Health care	1
Clinic cooperation	Close	5	Demand	Demand pull	4
	Some	2		Science push	4
	None	4		Both	3
Additional knowledge resources[1]	Within the university	4	Target user[1]	Research	6
	External	2		General health care	3
	None	6		Specialist care	8
				Intensive care	4
				Diagnostics	1
Planning			Innovation characteristics		
Formulation of project goals	Yes	4	Competing technology	Similar	3
	No	7		Not equal	1
				None	7
Meetings with collaboration partners	Regular	4	Trialability	High	9
	Sporadic	3		Low	1
	(no data)	4		Not foreseeable	1
Obedience to project schedule	High	2	Compatibility complexity, observability	Can not be drawn from the interview material	
	Moderate	5			
	Low	3			
	(no data)	1			

1. More than one alternative can be applicable to each project.

clinical trials. One project leader stated that the project was in an educational phase. Assessments of the technologies had been performed in a few cases, mostly when a competing technology is available on the market.

The industry partner is assumed to possess knowledge about rules and legislation regarding the projects. This is also the fact for patent issues, where the companies have contributed with expertise and financial means. Thus the patents are predominantly company owned. In a few cases there has been a clash between the researcher who wants to publish and the company interest in patenting the idea. Nevertheless, diffusion of some results has been achieved, mainly through conference contributions and papers. Since the time of the interviews dissertations have been completed.

A number of internal factors are found to be relevant for perceived advancement in the projects, including stable economy, proximity to clinical departments, positive feedback from collaboration partners, and extended competence area. Significant negative factors are changes in cooperation structure and delays because of personnel who leave the project. Although the cooperation is perceived as overall positive, there has been some disagreement in how to proceed with the project and at what pace. The external environment is predominantly described as positive. A cluster of related projects is perceived as beneficial and the opinion was expressed that experience from one project can be useful in another.

Innovation characteristics are to be further explored, but the innovations in question appears to have good trialability and most have a competitive advantage since there is no comparable technology available.

V. DISCUSSION

Engineering problem solving in small companies or by individuals comprises most of the innovation of medical devices. Thus it is of great importance that university knowledge and product ideas will be transferred to this innovative environment. An attempt to facilitate technology transfer is tried out in the publicly supported NIMED center. The cooperation structure seems to widen the knowledge base and provide a good working atmosphere. Physicians in the collaborating clinics play an important role. As potential end users they possess knowledge about the clinical need and can give important information in prototype development. Moreover, a period of learning can be necessary before a new device will function in the clinical setting. In purpose to shorten this period the physician's view is of great value.

Links between university and industry are of vital economic importance and contributes a lot to the working atmosphere. Economic gain is regarded the main incentive in innovation [10]. In case an invention does not have exploitation potential, it will never become an innovation at all. In the study material projects this role of economic gain is somewhat less pronounced. The gain does not always seem to be coupled directly to the invention, but to an extended competence network and some academic legitimacy in the company. Academic scientists are often content with consulting opportunities and hesitate to leave employment security for the uncertainty as an entrepreneur [6].

Different practices, strategies and attitudes regarding research work have been observed, in spite of a quite homogenous background of the interviewed project leaders. There is generally satisfaction with discoveries made and the scientific production. There may be a weakness, though, in definition and planning in some of the projects. In spite of the existence of written project descriptions, these were not perceived as project goals. This and the ongoing documentation habits have to be more sufficiently covered by further interviews. In reference [11] the most important factors "that influence the success or failure of projects" were ranked by TTOs (Technology transfer offices) according to their principles in funding R&D projects. In this "*clearly defined project goals*" was ranked the highest together with "*real and agreed need*".

Assessments have so far been performed to a limited extent in the NIMED projects. Competitive advantages compared to alternatives are tested during the innovation process and in cases a competing technology exists, it is used to see how the new device performs. General regulatory schemes regarding medical devices focus mainly on safety. Efficacy testing practices have so far varied in quality and clinical evaluation often includes ease of use and reliability.

The possibility to publish results is essential for the academic career. There is sometimes a clash between the academic researcher who wants to publish and the entrepreneur who

wants to patent the idea in order to exploit it on the market [12]. To be able to patent an idea, it must be original and new. If any publication is done, the possibility of patent protection is gone. In this early stage of innovation, though, it seems less important to acquire patent protection. On the contrary, the view has been expressed that it is a risk involved in early patenting. The basic idea can be picked up and used in another patent. Another reason to adopt a wait-and-see policy is the relatively long time-span of development, which shortens the effective patent life.

Technology transfer in this early phase is equally dependent on innovation characteristics as the later diffusion process. The original idea must be perceived as competitive and be consistent with professional norms and values. It is an advantage if R&D colleagues easily comprehend the concept. Observability of the technology is increased along with the amount of professional and public attention to the research problem, which facilitates funding and personnel recruitment.

The described technology transfer events are pictured mainly on basis of the interviews with the project managers, which implies that their views have had a dominant influence. It can also be hazardous to generalize the results to other areas of innovation. Characteristics of later innovation processes in the three groups of medical technologies differ in several aspects [13] and a logical assumption is that the research and development process differs in a similar way. Thus conclusions may be drawn only about the medical device group.

In order to increase validity the results will be discussed with the interviewees in a follow-up study and continuing study of documentation is also performed. The validity of method could be further increased by e.g. a systematic text analysis of the interview material by a multidisciplinary research team with representatives from the social sciences, medical profession and biomedical engineering.

VI. Conclusion

A. Innovation model

The model of innovation activities as a linear-sequential process is not valid in the investigated projects. Research work does at times return to the basic research stage and is often entering sidetracks. Division into "science-push" and "demand-pull" technologies is not applicable, as market demands seem to interact with accumulated scientific and engineering knowledge in most of the projects.

A potential economic gain of the innovation is not always the initiating power of R&D processes.

Clusters of related projects is fruitful to research work.

B. Technology transfer guidelines

Proximity to clinical departments (end users) facilitates testing of prototypes and valuable advice can be acquired from medical expertise. The external environment is of vital importance. The creation of a multidisciplinary discussion forum is equally important as proximity to colleagues in related projects.

Long-range planning of- and guaranteed financing is essential for the working atmosphere.

A starting point in the early innovation assessment is a concept test to find out if the idea has been tried before. Mapping of the market can be achieved by questioning personnel in the potential end user clinical environment.

Small pilot studies is the most valuable form of assessments of performance, efficacy and user acceptability regarding evolving technologies, since assessments will soon be obsolete. Production technology assessment is preferably done alongside with prototype development, in the view of commercial exploitation of the product.

Conclusions drawn from the study will be used in production of an improved model of innovation and technology transfer in the field of biomedical engineering. Generally little attention is paid, within the projects, to how scientific knowledge and technologies are produced. Our study can be useful in planning and evaluation of research projects. The intention is to feedback results to the projects, which in extension will benefit academic research and health care development as well as the medical device industry.

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